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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,941	09/19/2003	Kurt David Krueger	13033.10US01	6541

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P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER

WALKER, AMANDA H

ART UNIT	PAPER NUMBER
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3709

MAIL DATE	DELIVERY MODE
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/665,941

Applicant(s)

KRUEGER ET AL.

Examiner

Amanda H. Walker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02/02/2004, 02/24/2004, 02/04/2005, 10/13/2005, 01/23/2006, 10/13/2006.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeung et al (WO 00/40159).

Regarding Claims 1 and 5-6: Yeung et al. teaches an apparatus comprising a handle 6 with a predetermined geometry, an actuator 12, a needle (distal end of 7) with a distal tip and bore (FIGS. 7 and 8), an implant/fastener 13 disposed within a bore (FIGS. 7 and 8), and a cartridge body/cartridge 62 with a proximal end 9 adapted to align and couple to the geometry of the handle (FIGS. 12 and 14). A release is inherent since the handle and cartridge are not unitary.

Regarding Claims 2-4: Yeung et al. teaches an actuator 12, an obturator/distal end of rod 10 and a driver/middle of rod 10 which both go into the bore (FIG. 12).

Regarding Claim 7: Yeung et al. teaches a fastener/implant that is adapted to alter a dynamic response/fasten loose tissue (7:35-40 and 8:1-5).

Regarding Claim 13: Storage within a sterile container is an inherent property of surgical tools.

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Regarding Claims 28 and 29: Yeung et al. teaches that the handle has a pistol grip 6 with a textured surface and a plurality of parallel ribs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung et al. (WO 00/40159) as applied to claim 1 above and further in view of first and second embodiments of Knudson et al. (U.S. Patent Application Publication No. 2001/0037133).

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Regarding Claim 8: Yeung et al. does not teach that the implant includes a tissue in-growth layer. However, a first embodiment of US PUB '133 teaches an implant with a tissue in-growth layer (para. 0105). Yeung et al. and the first embodiment of US PUB '133 are combinable because they are from the same field of endeavor, namely, bodily implants. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the tissue in-growth layer of the first embodiment of US PUB '133, and one would have been motivated to do so in order to encourage stabilization and immune acceptance of the implant.

Regarding Claim 9: Yeung et al. does not teach that the implant is bigger than the bore in which it is held. However, a second embodiment of US PUB '133 teaches an implant that expands upon release/is a size greater than the bore that it is held in (FIGS. 22 and 23). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the expandable property of the second embodiment of US PUB '133, and one would have been motivated to do so in order to encourage deformation of the soft palate and reduce snoring (US PUB '133, para. 0078).

Regarding Claim 10: Yeung et al. does not teach that the implant is formed of multiple fibers including those of the tissue in-growth material. However, the first embodiment of US PUB '133 teaches an implant that is formed of multiple fibers including those of tissue in-growth material (para. 0105). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the multiple fibers of tissue in-growth material taught by the first embodiment of

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USPUB '133, and one would have been motivated to do so in order to provide more holes for tissue in-growth, which is desirable because it encourages stabilization and immune acceptance of the implant.

Regarding Claims 11-12: Yeung et al. does not teach that the fibers are braided/twisted together along the length of implant. However, the first embodiment of USPUB '133 teaches fibers that are braided/twisted together along the length of implant (para. 0105). The terminal ends are therefore at opposite sides of the implant (FIG. 45b). At the time of the invention, it would be obvious to a person having ordinary skill in the art to modify the implant taught by Yeung et al. with the braiding/twisting together along the length of the implant, and one would have been motivated to do so in order to keep the implant fibers from detaching from the implant and causing a detrimental immune response.

Claims 14-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung et al. (WO 00/40159) in view of Sawyer (U.S. Patent No. 4,065,816) and first and second embodiments of Knudson et al. (U.S. Patent Application Publication No. 2001/0037133).

Regarding Claim 14, 18, 19, and 26, and 27: Yeung et al. teaches an kit comprising a handle 6 with a predetermined geometry, an actuator 12, a needle (distal end of 7) with a distal tip and bore (FIGS. 7 and 8), an implant/fastener 13 disposed within a bore (FIGS. 7 and 8), and a cartridge body/cartridge 62 with a proximal end 9 adapted to align and couple to the geometry of the handle (FIGS. 12 and 14). A release is implicit

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since the handle and cartridge are not unitary. Storage within a sterile container is an implicit property of surgical tools.

Yeung et al. does not teach common container for the cartridge and the handle. However, Sawyer teaches a common container for a cartridge and handle (FIG. 1). Yeung et al. and Sawyer are combinable because they are from the same field of endeavor, namely, implant delivery devices. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the kit of Yeung et al. with the common container taught by Sawyer, and one would have been motivated to do so due to convenience and a reduction in operating time, which reduces the possibility of infection.

Yeung et al. does not teach that the kit has a plurality of cartridges. However, Sawyer teaches a kit with a plurality of cartridges (34, 46, 36, 44, and 42 of FIG. 1). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the kit taught by Yeung et al. with the plurality of cartridges taught by Sawyer, and one would have been motivated to do so in order to construct a rod like implant delivery device.

Regarding Claims 15-17: Yeung et al. teaches an actuator 12, an obturator/distal end of 10, and a driver/middle of rod 10 which both go into the bore (FIG. 12).

Regarding Claim 20: Yeung et al. teaches a fastener/implant that is adapted to alter a dynamic response/fasten loose tissue (7:35-40 and 8:1-5).

Regarding Claim 21: Yeung et al. does not teach that the implant includes a tissue in-growth layer. However, a first embodiment of US PUB '133 teaches an implant with a

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tissue in-growth layer (para. 0105). Yeung et al. and the first embodiment of US PUB '133 are combinable because they are from the same field of endeavor, namely, bodily implants. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the tissue in-growth layer of the first embodiment of US PUB '133, and one would have been motivated to do so in order to encourage stabilization and immune acceptance of the implant.

Regarding Claim 22: Yeung et al. does not teach that the implant is bigger than the bore in which it is held. However, a second embodiment of US PUB '133 teaches an implant that expands upon release/is sized greater than the bore (FIGS. 22 and 23). At the time of the invention, it would be obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the expandable property of the second embodiment of US PUB '133, and one would have been motivated to do so in order to encourage deformation of the soft palate and reduce snoring (US PUB '133, para. 0078).

Regarding Claim 23: Yeung et al. does not teach that the implant is formed of multiple fibers including those of a tissue in-growth material. However, the first embodiment of US PUB '133 teaches an implant formed of multiple fibers including those of tissue in-growth material (para. 0105). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant of Yeung et al. with the multiple fibers of tissue in-growth material taught by the first embodiment of US PUB '133, and one would have been motivated to do so in order to provide more holes for tissue in-growth, which is desirable because it encourages stabilization and immune acceptance of the implant.

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Regarding Claims 24-25: Yeung et al. does not teach that the fibers are braided/twisted together along the length of implant. However, the first embodiment of US PUB '133 teaches fibers that are braided/twisted together along the length of implant (para. 0105). The terminal ends are therefore at opposite sides of the implant (FIG. 45b). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the implant taught by Yeung et al. with the braiding/twisting together along the length of the implant, and one would have been motivated to do so in order to keep the implant fibers from detaching from the implant and causing a detrimental immune response.

Other prior art considered applicable to the instant claims but not used in these rejections can be found in the enclosed document entitled "Notice of References Cited".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 4 of U.S. Patent '105 teaches a handle, a cartridge with a proximal end adapted to align and couple to the geometry of the handle, an actuator, a needle with a distal tip and axial bore, an implant disposed within the bore, and an obturator and driver which both go into the bore.

Claims 5 and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 6 of U.S. Patent '105 teaches that the handle has a predetermined geometry and that the cartridge has a proximal end adapted to align and couple to the geometry of the handle. Claim 6 also teaches a release.

Claim 7 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because Claim 7 of U.S. Patent '105 teaches that the implant is adapted to alter a dynamic response.

Claims 8, 10, and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 11 of U.S. Patent '105 teaches that the implant includes tissue in-growth material, and may be formed of multiple fibers including those of the tissue in-growth material. The multiple fibers are twisted together along the length of the implant and their terminal ends are at opposite sides of the implant.

Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 9 of U.S. Patent '105 teaches that the implant is bigger than the bore.

Claim 12 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 12 of U.S. Patent '105 teaches that the multiple fibers are braided.

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Claim 13 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 13 of U.S. Patent '105 teaches that the cartridge is contained within a sterile container.

Claims 14 and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 14 of U.S. Patent '105 teaches a kit with a handle having an actuator, a cartridge having a small biocompatible implant, a needle with a distal tip and an axial bore, an implant disposed within the bore, a proximal end of the cartridge adapted to couple to handle, and a container.

Claims 15-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 17 of U.S. Patent '105 teaches a kit with an obturator carried within the bore, and an actuator with a driver, the driver being positioned to be received by the bore when cartridge is coupled.

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Claims 18 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 19 of U.S. Patent '105 teaches a handle, the handle coupling having a predetermined geometry. The proximal end of the cartridge also has a cartridge coupling to be mated to the predetermined geometry. The cartridge and handle are aligned.

Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 20 of U.S. Patent '105 teaches that the implant is adapted to alter a dynamic response.

Claims 21, 23, and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 24 of U.S. Patent '105 teaches that the implant includes tissue in-growth material, and may be formed of multiple fibers including those of the tissue in-growth material. The multiple fibers are twisted together along the length of the implant and their terminal ends are at opposite sides of the implant.

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Claim 22 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 22 of U.S. Patent '105 teaches that the implant is sized slightly greater than the bore.

Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 6,899,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 25 of U.S. Patent '105 teaches that the multiple fibers are braided.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda H. Walker whose telephone number is (571)270-3296. The examiner can normally be reached on 9-4, M-Th, EST.

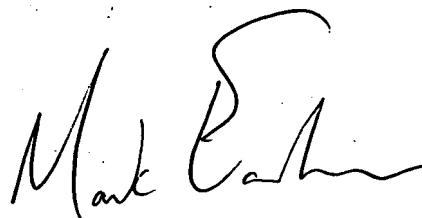
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW

8-21-07

A handwritten signature in black ink, appearing to read "Mark Eashoo".

MARK EASHOO, PH.D.
SUPERVISORY PATENT EXAMINER

04/ Sep/07